Cooperation between medical doctors and engineers for developing advanced medical devices

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Abstract- **In this paper, I look at one factor that affects the performance of R & D of advanced medical technologies and medical devices: cooperation between medical doctors and engineers. I examine perceptions on the cooperation between medical doctors and engineers in U.S., Japan and Germany based on a case study on artificial vision system and a survey. In particular, I look at the differences in perception between medical doctors and engineers across these three countries.***

I. INTRODUCTION

The size of the medical device industry in the world was about 200 billion dollars in 2007. The market share of the U.S., Europe and Japan was 42 percent, 34 percent and 10 percent respectively. Firms, researchers and governments in those countries and regions are today competing for success in an industry where products are technically advanced and highly value-added, and contribute to the health of their society and people.

In this study, I look at the environment around the R&D of advanced medical technologies and medical devices in the U.S., Germany and Japan. Although there are various factors that affect the successful development of medical devices, I focus on only one: cooperation between medical doctors and engineers. I have three research questions on the topic:

1. How is the cooperation between medical doctors and engineers important for the development of medical devices?
2. How is it possible to promote the kind of cooperation between medical doctors and engineers that can lead to the development of advanced medical devices? What factors promote or limit the cooperation?
3. Are there any differences in perceptions regarding the first and second questions among medical doctors and engineers across countries?

In section II, I explain the methodology. I show the results in section III, and analysis in section IV. In section V, I explain the implication and future direction.

II. METHODOLOGY

The research method I used for approaching the research questions includes a case study on development of artificial vision system, and a survey for medical doctors and medical engineering researchers at universities.

II-1. Interviews

There are currently about 50 research teams that are developing artificial vision, which is a tiny electric device inserted into the eye for restoring vision in patients suffering from blindness due to retinitis pigmentosa (RP) or age-related macular degeneration (AMD). The research efforts in the U.S., Germany and Japan are in an advanced stage, and they are conducting, or preparing for, clinical trials to market the product in the next five to six years. In the interview, I focused on this R & D area in order to compare the level of cooperation between medical doctors and engineers across countries.

In the interview, I asked how the researchers organized and maintained a multidisciplinary research team including medical doctors, engineers and company researchers and sustained the efforts of the team at a high level. Based on qualitative information collected from the interviews, I designed the questionnaire for the survey.

I conducted the interviews with five to ten researchers in the U.S., Japan and Germany respectively. In addition, I used the results of the interviews to complement and interpret findings from the survey. In interviews, I asked the following questions:

- What kind of R & D had been conducted so far? (areas, research team, market, funding, etc.)
- What kind of cooperation was observed between medical doctors and engineers regarding the R & D?
- What factors promoted or limited the cooperation?
- What measures were necessary for promoting cooperation?
- What kind of cooperation did R & D have from firms?
- How did they evaluate government policy and regulation framework on medical equipment in their country?

I conducted interviews with ten researchers in Japan, at the engineering and medical departments of universities and firms, in September and October 2008. I conducted six interviews in the U.S. in December 2008 and five interviews in Germany in January 2009.

II-2. Survey

I asked university professors in the medical and engineering departments in the U.S., Japan and Germany about their perceptions and opinions on the current level of cooperation between medical doctors (clinicians) and engineers for developing advanced medical technologies. In addition, I asked them about factors that were important for promoting cooperation between medical doctors and engineers, and the effective government policies that could promote cooperation, along with other relevant issues related to development of

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advanced medical technologies.

Regarding medical doctors, we chose university professors or associate professors specializing in ophthalmology since the case study was related to ophthalmology. I chose this specialty in order to make the survey data more comparable across the three countries with findings from the interviews. Regarding engineers from the three countries, I chose university professors or associate professors specializing in medical engineering, medical devices or medical technologies. The number of professors and associate professors chosen from one university was restricted to five in order to make the data more representative.

I sent 991 questionnaires to researchers at the medical and engineering departments in the U.S., Japan and Germany.

I sent the questionnaire during June 27-29, 2009, and asked them to post the completed form by July 21, 2009. Since it usually takes a week for a letter sent from Tokyo to arrive in the U.S. or Germany, the respondents in Japan were given about three weeks while around two weeks were given to respondents from the U.S. and Germany. The reply could be either the paper version or the Internet-based one.

The questions were posted on Zoomerang, an Internet-based survey tool. The URL of the survey page was given in the questionnaire.

III. RESULTS

III-1. Interviews

In the interviews, almost all researchers noted that effective cooperation was the key to the successful development of advanced medical devices. Some important factors mentioned in initiating and maintaining cooperation were government funding, education in the field of medical engineering, historical cooperative relationship among institutions, research clusters to find appropriate researchers with relative ease, leadership and personality of participants, regulation and the role of firms.

There are about 50 research teams on artificial vision system, in the U.S., Germany, Japan, Taiwan, China, Belgium, Switzerland, etc (see TABLE 1). I conducted interviews with team members and persons from these research teams who know about the process, in the U.S., Germany and Japan. R & D in the U.S. and Germany started in the late 1980s and early 1990s, and is in the commercialization stage currently. Japan is a late entrant in this field, and was strongly supported by the Japanese government in the early to mid 2000s.

The following is a brief summary of the main findings from the interviews.

1) Government funding

There has been no big national project in the U.S. on artificial vision, but the government, including the National Institute of Health (NIH) and the National Science Foundation (NSF), supports the R & D continuously and has invested significant money in the field since the late 1980s. In Germany, there was strong support from the Federal Ministry of Education and Science (BMBF) from 1994. After the government support ended in 2003, R & D has been conducted mainly by funding from private firms (Retina Implant, and Intelligent Medical Implant). No major support from government is provided in the commercialization process. In Japan, there was strong government financial support from the New Energy and Industrial Technology Organization (NEDO), the R & D funding arm of Ministry of Economy, Trade and Industry (METI) during 2001 and 2005. However, R&D on this research topic started late compared with the U.S. and Germany. Funding is important for the cooperative relationship among members to continue. Lack of funding affects cooperation.

2) Education in medical engineering

In the U.S. and Germany, there are many education programs on medical engineering at universities. In Japan, there are very few education programs in medical engineering. Most of the programs were started in the past five years in Japan. Programs in medical engineering not only provide education to students who want to do research in the field of medical technology, but also function as a place to conduct R & D on medical devices in cooperation with medical doctors.

3) Regional factor and historical cooperative relationship

In the U.S., a historically cooperative relationship exists between medical schools and engineering departments, for example, between Harvard Medical School and MIT. There are regional advantages in Boston, California, etc. History is important. A cooperative relationship takes time to build.

4) Leadership and personality

Most members pointed out the importance of leadership of research leaders and the personality of members as a condition for good cooperation. Personality is important and dominant figures are not liked by others.

TABLE 1
Major R & D teams on artificial vision (retinal stimulation)

Country	**Organization**	**Method**
U.S.	University of Southern California University of California, Santa Cruz Second Sight, Inc., etc.	Epi-retinal stimulation Extraocular camera
U.S.	Harvard Medical School MIT	Epi-retinal stimulation Extraocular camera
Germany	University of Bonn Fraunhofer Institute Biomedical Technik (IBMT), etc.	Epi-retinal stimulation Extraocular camera
Germany	University of Tübingen, etc.	Sub-retinal stimulation Intraocular camera
Japan	Osaka University (medical school, engineering department) Nara Institute of Science and Technology Nidek Inc., etc.	Suprachoroidal-transretinal stimulation Extraocular camera
Japan	Tohoku University	Epiretinal stimulation Intraocular camera

5) Regulation

In Germany, regulation on medical devices is not very tight, but it is difficult to obtain coverage for a medical device through health insurance. In the U.S. and Japan, regulation is tight. It is necessary to get significant amount of funding either from the government or from venture capital to conduct clinical trials in the U.S. The situation is the same in Japan.

6) Involvement of firms

The role of private firms is important for commercialization of products. In Japan, one firm is performing R & D using its own research funding. Firms with experience in medical technology are important. Private firms are also involved in the development of commercial products in the U.S. and Germany.

III-2. Surveys

TABLE 2 shows the number of responses and response rates by country and department. The number of responses was 127 and response rate was 12.8% in total. In general, response rates from professors in medical departments were low. One possible reason may be that not all professors in the medical departments specializing in ophthalmology are involved in the R & D of medical devices. In the engineering department, I sent questionnaire only to professors specializing in medical technologies and medical devices; hence the better response.

The following summary of the survey results is based on the responses as of August 30, 2009.

III-2-1. Organization and profession

There were a total of 127 respondents in this survey: 66, 30 and 31 from Japan, the U.S., and Germany, respectively.

TABLE 3 shows the respondents' organization. One third of the respondents belong to the medical department of universities, and the rest two thirds belong to the engineering or medical engineering departments of universities. The proportion of respondents from engineering and medical engineering departments is large in Japan, and the proportion of respondents from medical departments is large in Germany.

TABLE 4 shows that about one third of respondents are medical doctors and two thirds of the respondents are engineers. The proportion of medical doctors is lower in Japan, about 24%, and higher in the respondents who currently reside in the U.S. and Germany. Comparing TABLE 3 and TABLE 4, we find that three medical doctors in Japan and one medical doctor in the U.S. do not work for medical departments.

TABLE 2
Number of questionnaire sent, and responses

Country	Department	Numbers sent	No of responses	Response rate
Japan	Medical department	197	13	6.6%
	Engineering department	158	53	33.5%
United States	Medical department	174	11	6.3%
	Engineering department	167	19	11.4%
Germany	Medical department	154	17	11.0%
	Engineering department	141	14	9.9%
Total		991	127	12.8%

Note: Engineering department includes engineering department, medical engineering department, or medical engineering research center.

TABLE 3
Respondents' organizations

	Medical department	Engineers department	Medical engineering department	Other	Total
Japan	13 (20%)	31 (47%)	16 (24%)	6 (9%)	66 (100%)
United States	11 (37%)	12 (40%)	3 (10%)	4 (13%)	30 (100%)
Germany	17 (55%)	7 (23%)	5 (16%)	2 (6%)	31 (100%)
Total	41 (32%)	49 (39%)	24 (19%)	12 (9%)	127 (100%)

Note: Number in parenthesis shows the proportion of each department for each of the countries.

TABLE 4
Respondents' profession

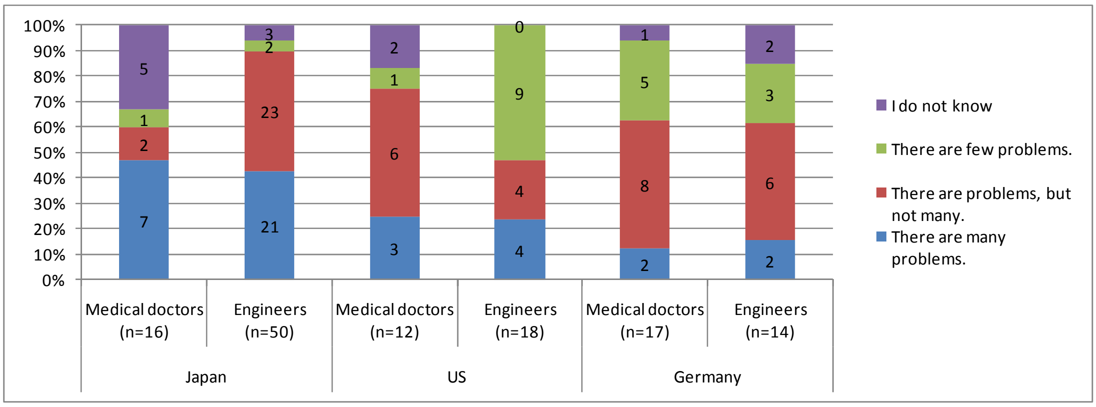
	Medical doctors	Engineers	Total
Japan	16 (24%)	50 (76%)	66 (100%)
United States	12 (40%)	18 (60%)	30 (100%)
Germany	17 (55%)	14 (45%)	31 (100%)
Total	45 (35%)	82 (65%)	127 (100%)

III-2-2. Perceptions on conditions of R & D activities of medical technologies / devices

Respondents were asked whether there were problems related to R & D activities of medical technologies / devices in the country where they work.

The proportion of respondents who perceive problems is much higher in Japan than in the U.S. or Germany. A significant proportion of respondents chose "there are few problems" in the U.S. and Germany as is seen in Fig. 1. In Japan, engineers saw more problems than medical doctors, while in the U.S. medical doctors saw more problems than engineers. The proportion is about the same between medical doctors and engineers in Germany.

Next, respondents were asked about their perception on the level of cooperation between medical doctors and engineers compared to the other two countries in those three countries. In Fig. 2, we see that majority of respondents in Japan chose "lower level," while respondents in the U.S. and Germany did not think that the level of the cooperation in the country was lower than in other countries. There is no significant difference in the perception between medical doctors and engineers in the three countries.



Note: Number in the bar shows the number of respondents.

Fig. 1. Problems on R & D activities of medical technologies / devices in your country

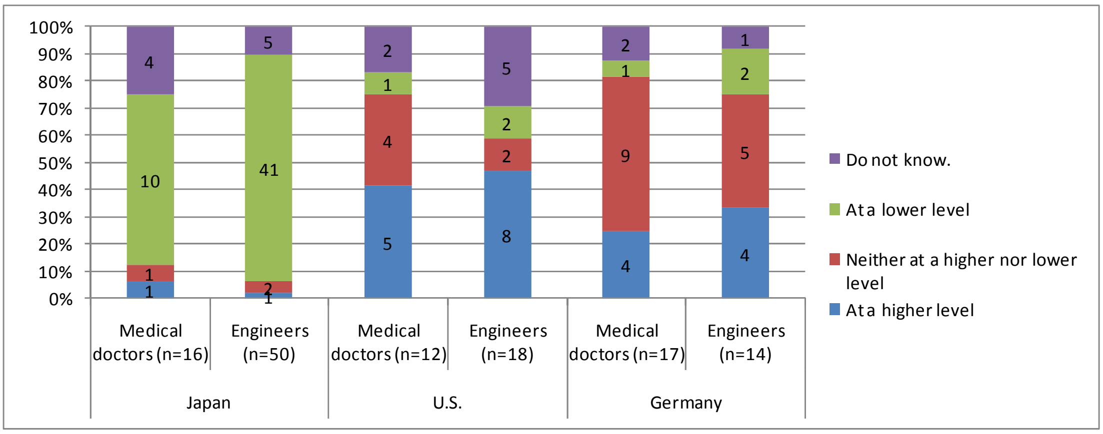


Fig. 2. Compared to other countries, do you think that the cooperation between medical doctors and engineers in the country is at a higher level or at a lower level?

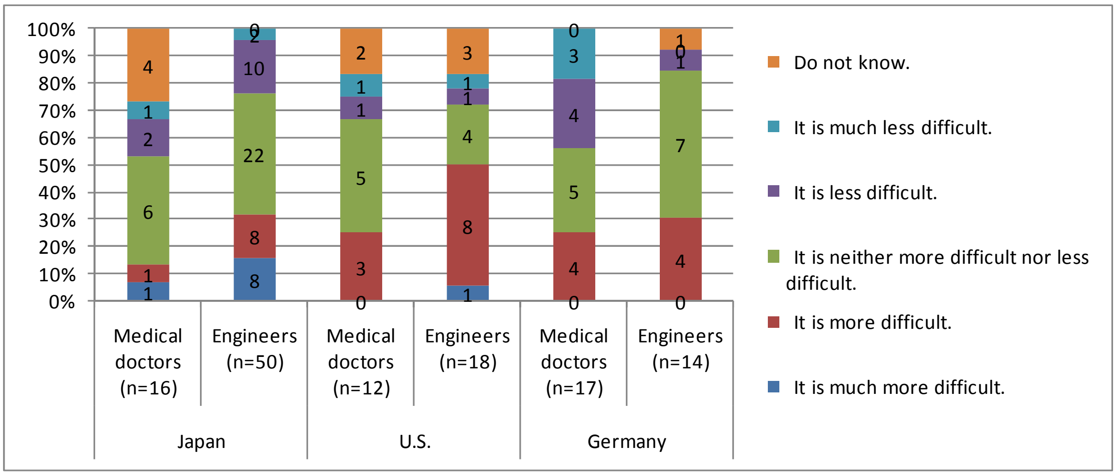


Fig. 3. Whether a research project involving cooperation between medical doctors and engineers is more difficult than a multidisciplinary research project

III-2-3. Perception on difficulty of cooperation between medical doctors and engineers

Respondents were asked whether a research project involving cooperation between medical doctors and engineers is more difficult than other types of multidisciplinary research projects. Fig. 3 shows the survey result of medical doctors and engineers in the U.S., Japan and Germany. Comparing the three countries, the proportion of respondents who think that cooperative projects between medical doctors and engineers are more difficult than other types of multidisciplinary projects is higher in the U.S. than in Japan and Germany. The proportion of “more difficult” and “much more difficult” is 40% in the U.S., 28% in Japan and 28% in Germany.

TABLE 5 compares the difference of opinions between medical doctors and engineers in this respect in the three countries. The proportion of engineers who think that cooperation is more difficult is larger than that of medical doctors in all three countries. In Japan and Germany, the proportion of medical doctors who think that cooperation with engineers is less difficult is even larger than those who think it more difficult. In general, medical doctors tend to think that the cooperation between medical doctors and engineers is not more difficult while engineers think that it is more difficult than other types of multidisciplinary R & D projects.

III-2-4. Factors that can contribute to the success of cooperation between medical doctors and engineers

Respondents were asked to select up to three choices from the list of possible factors that can contribute to the success of cooperation between medical doctors and engineers. I made the list based on the information derived from the interviews. The order of the choices was randomized in the Internet-based survey.

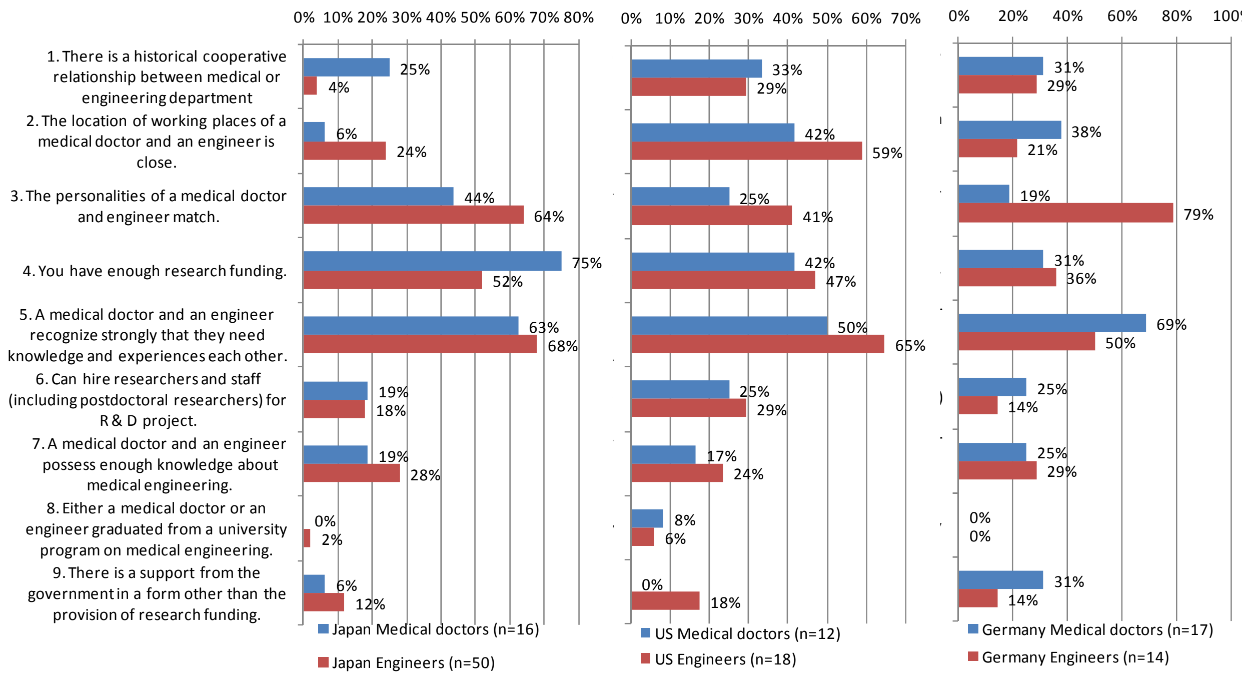
Fig. 4 shows the results by country and profession. The proportion of choosing choices “3. The personality of a medical doctor and an engineer matches,” “4. You have enough funding,” and “5. A medical doctor and an engineer recognize strongly that they need knowledge and experiences each other” are high in all countries. The proportion on funding is especially high in Japan. In addition, the proportions on choices related to personality matching and mutual necessity of each other’s knowledge are higher in engineers’ responses than medical doctors’ responses. Choice 8 regarding education in medical engineering is not high in the three countries.

The characteristics of answers from the U.S. or Germany were quite different from Japan; the proportion of first choice on the importance of historical relationship between medical school and engineering department of universities was high in the U.S. and Germany and low in Japan. In addition, the second choice on the importance of closeness of locations of working places of a medical doctor and an engineer was high in the U.S.

TABLE 5
Difference in opinions between medical doctors and engineers on the difficulty of cooperative research project between medical doctors and engineers compared with other types of multidisciplinary projects

	Medical doctors		Engineers	
	More difficult	Less difficult	More difficult	Less difficult
Japan	14%	20%	32%	24%
United States	25%	16%	50%	12%
Germany	25%	44%	31%	8%

Note: “More difficult” refers to both “Much more difficult” and “More difficult”, and “Less difficult” refers to both “Much less difficult” and “Less difficult” in responses.



Note: Japan – left graph, U.S. – center graph, Germany– right graph
Fig. 4. Factors that can contribute to the success of cooperation between medical doctors and engineers

III-2-5. Factors that can contribute to the failure of cooperation between medical doctors and engineers

Respondents were asked to choose up to three factors that can contribute to the failure of cooperation between medical doctors and engineers. I asked this question because not being able to satisfy the factors important for the success of an R & D project does not necessarily lead to a failure of the project. I made the list based on information derived from the interviews.

In Fig. 5, the first option on lack of knowledge, the fifth option on lack of funding and the 12th option on lack of commitment are high in the three countries. Option 12 is especially high in the U.S. In addition, the proportion for this choice is higher among engineers than among medical doctors in Japan, while the proportion is about the same for engineers and medical doctors in the U.S. and Germany.

Option 2 on difference in culture or value system is higher among engineers than among medical doctors. This is especially high in Japan, both among engineers and medical doctors. Option 6 on lack of flexibility in using research funding is high in Japan, and low in the U.S. Option 9 on lack of supporting administrative staff is low in the U.S. compared to Japan and Germany.

III-2-6. Role of government in promotion of medical technology R & D

Respondents were asked whether the role of government is important for promotion of development of medical technology and medical devices (Fig. 6).

The proportion of choosing "very important" and "important" is higher in Japan than in the U.S. and Germany. However, it is also relatively high (more than 50%) in the U.S. and Germany. The proportion is higher among medical doctors than engineers in Germany, but is about the same among medical doctors and engineers in Japan and the U.S.

Next, respondents were asked to choose up to three roles which they think are important for the government.

In Fig. 7. option 1 on provision of R & D funding is high in all three countries. As to other choices, the pattern is different among countries. Option 2 on national R & D project is relatively high in Japan and Germany compared to the U.S. Option 5 on regulation is high in Japan, while it is not so in the U.S. (engineers) and Germany. Option 8 on support for exchange of medical doctors and engineers is high in the U.S. and Germany, but not that high in Japan. In general, there is no pattern regarding differences in opinions between medical doctors and engineers, which may be common to all three countries.

As to option 4 on promotion of education program in medical engineering, it is not very high in Japan, although such education programs are not as well developed in Japan as in the U.S. and Germany.

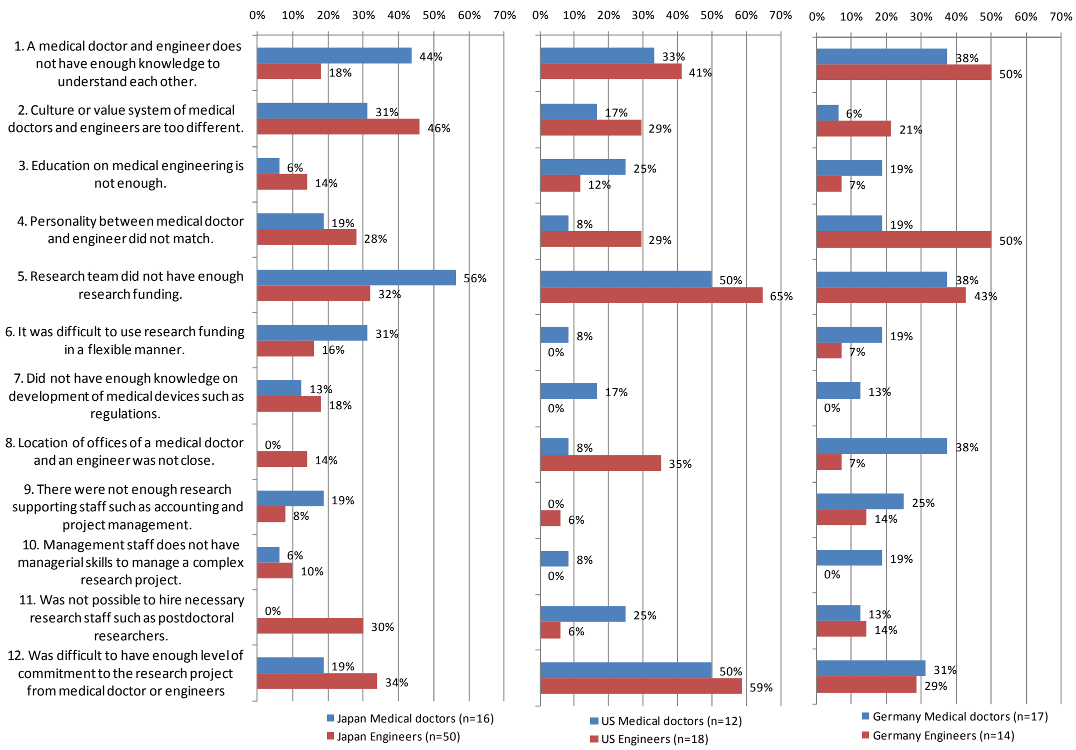


Fig. 5. Factors that can contribute to the failure of cooperation between medical doctors and engineers

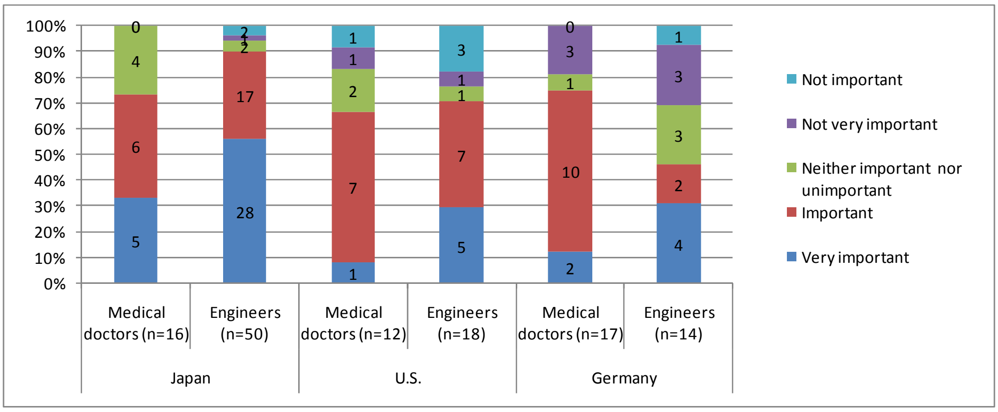
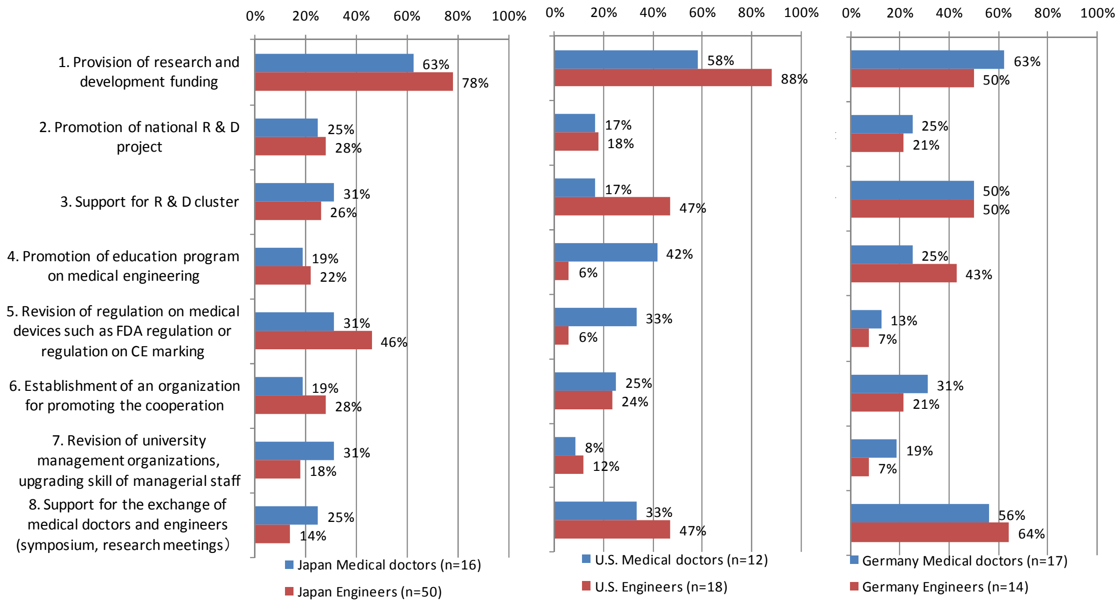


Fig. 6. Do you think that role of government is important for promotion of medical technology?



Note: Japan – left graph, U.S. – center graph, Germany– right graph

Fig. 7. What kind of roles of government is important?

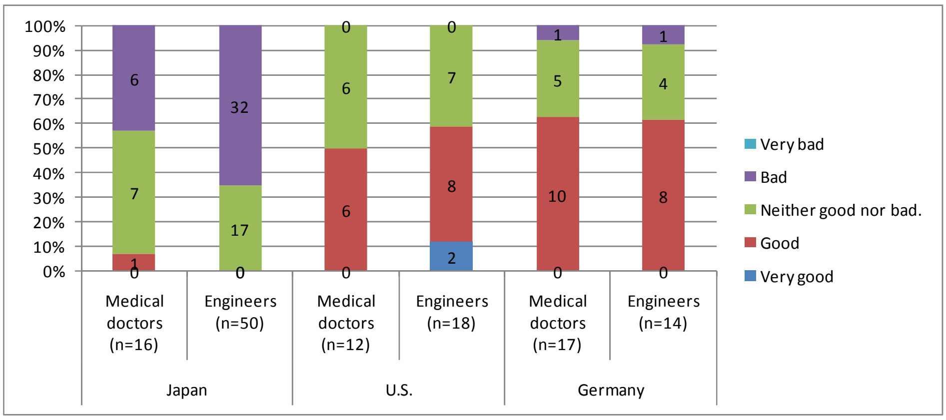


Fig. 8. How do you evaluate policy and institutions in your country in terms of the promotion of cooperation between medical doctors and engineers?

In the next question, respondents were asked to evaluate the policies and institutions in their country of residence for promoting cooperation between medical doctors and engineers.

As seen in Fig. 8., policies were not evaluated highly in Japan. The proportion of choosing “Bad” is much lower and “Good” much higher in the U.S. and Germany than in Japan. There was not much difference between the answers of medical doctors and engineers in each of the countries.

IV. ANALYSIS

For analyzing the results of the case study and the survey, I propose a model on cooperation between clinicians and engineers, based mainly on the management of tacit and explicit knowledge.

From a microscopic perspective, new knowledge is created on the basis of exchange and transfer of knowledge of participants in a research project. Participants in an R & D project draw on their individual knowledge. The kind of knowledge that is exchanged and transferred in the cooperation between medical doctors and engineers includes both *explicit knowledge*, which is transferred among participants easily by documents and verbal communication, and *tacit knowledge*, which is difficult to transfer and can be transferred only by way of apprenticeship, social relationship or interactions on a long term. It might be frustrating for medical doctors and engineers to communicate their own tacit knowledge as well as understand the tacit knowledge of their counterparts. If so, the difficulty is a big hurdle for the good cooperation necessary for developing advanced medical devices.[1]

Knowledge, in this case, is a concept different from *information* defined as follows:[2]

> Knowledge is a fluid mix of framed experience, values, contextual information, and expert insight that provides a framework for evaluating and incorporating new experiences and information. It originates and is applied in the minds of knowers. In organizations, it often becomes embedded not only in documents and repositories but also in organizational routines, processes, practices, and norms.

Michael Polanyi, who proposed the concept, was originally trained as a medical doctor before becoming a chemist. He frequently refers specifically to the education of medical doctors while explaining the concept of tacit knowledge in his book *Personal Knowledge* published in 1958. The following is a remark from the book:

> Connoisseurship, like skill, can be communicated only by example, not by precept. To become an expert wine-taster, to acquire knowledge of innumerable different blends of tea or to be trained as a medical diagnostician, you must go through a long course of experience under the guidance of a master. Unless a doctor can recognize certain symptoms, e.g. the accentuation of the second sound of the pulmonary artery, there is no use in his reading the description of syndromes of which this symptom forms part. He must personally know that symptom and he can learn this only by repeatedly being given cases for auscultation in which the symptom is authoritatively known to be present, side by side with other cases in which it is authoritatively known to be absent, until he has fully realized the difference between them and can demonstrate his knowledge practically to the satisfaction of an expert.[3]

From a macroscopic perspective, there are many social and economic factors that can affect cooperation between medical doctors and engineers, including regulation on medical devices R&D, government support, institutions such as health insurance, etc. In other words, cooperation in medical devices R & D is conducted in *sectoral system of innovation*, specific to the development of medical devices and medical technologies. According to Malerba [3], innovation in a sector is affected by 1) knowledge and technology, 2) actor and network and 3) institutions.[4]

From the “model” above, for example, the following propositions could be derived:

1. Medical engineering education can reduce the tacitness of knowledge both for medical doctors and engineers. However, the difficulty in transferring knowledge would still remain since an engineer cannot become a medical doctor.
2. Historical relationship, more frequent interactions among medical doctors and engineers or good personality matches can be effective for overcoming the barriers caused by tacitness of knowledge.
3. Experiences of cooperation lead to more effective cooperation, because more cooperation leads to less tacitness of knowledge.
4. If medical doctors are too busy, in clinical practice or teaching, to have enough time for commitment to an R & D project on medical devices, it makes the process of communication and knowledge transfer much more difficult, often to such a degree as to make the project fail.

The following is the list of important findings of the study from subsection III-2.

1. Cooperation between medical doctors and engineers is perceived to be difficult by respondents in the U.S. as well as in Japan and Germany. – III-2-3
2. In all three countries, cooperation is perceived to be more difficult by engineers than by medical doctors. – III-2-3
3. In all three countries, matching of personalities of members and necessity of each other’s knowledge are perceived to be more important by engineers than by

[1] A.A.Arntzen-Bechina, C.A.D. Leguy, A Model of Knowledge Sharing in Biomedical Engineering: Challenges and Requirements, *Journal of Business Chemistry*, Vol.4 Issue 1, January 2007.

[2] T. Davenport and L. Prusak, *Working Knowledge: How organizations manage what they know*, Harvard Business School, 1998. p.5.

[3] Michael Polanyi, *Personal Knowledge: Towards a Post-Critical Philosophy*, 1958. University of Chicago Press. Pp.54~55.

[4] Franco Malerba, “Introduction,” in *Sectoral Systems of Innovation: Concepts, Issues, and Analyses of Six Major Sectors in Europe*, edited by Franco Malerba, Cambridge University Press, 2004, pp.1-5.

medical doctors. –III-2-4

4. In the U.S. and in Germany, historical relationship and distance of location of medical doctors and engineers are perceived to be important. –III-2-4
5. In all three countries, commitment of members is perceived to be an important factor for the success of a project. –III-2-5
6. In all countries, difference in cultures and value systems is perceived to be a more important factor for failure of a research project by engineers than by medical doctors. –III-2-5
7. In all three countries, funding is perceived to be important. –III-2-6

I could not find any contradiction between these results and the propositions stated above. Although there are tacit elements in the fields of both engineering and medical science, engineers perceive more difficulty in understanding and using medical knowledge during R & D on medical technology.

V. IMPLICATION AND FUTURE DIRECTION

V-1. Implication

Fig. 9 shows that there are three elements that are related to the promotion of cooperation between medical doctors and engineers.

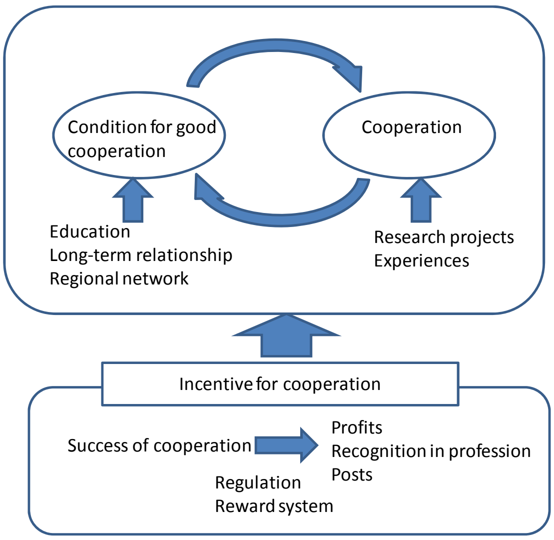


Fig. 9. Relation among Cooperation, Condition for good cooperation, and incentive for cooperation

First element is cooperation itself. Second element is conditions for realizing good cooperation. The conditions for good cooperation are historical relationship between medical and engineering departments of universities, education in medical engineering (transfer of tacit knowledge) and regional network, all of which are important for a good, productive cooperative relationship. . Experience of cooperation itself is a strong promoting factor for good cooperation in the future. These two elements strengthen and promote each other. Cooperation experiences are given by research projects or research funding.

Third element is an incentive system for cooperation. If success of cooperation for developing medical devices gives researchers financial and professional rewards, it provides them with an incentive to participate in or initiate cooperation. For an incentive system to work, it is necessary to think of a regulation system for the development of medical devices or of a reward system both financially and professionally.

It would be necessary to focus on each of these three elements for promoting cooperation.

V-2. Future direction

In this paper, I did a case study on the development of artificial vision and a survey involving professors from medical schools and engineering departments in the U.S., Japan, and Germany. The limitations of the study are that I did a case study for only one case and the number of samples in the survey is not large. In order to get a stronger result, it is necessary, first, to do case studies on more cases of R & D of medical devices, and second, to do more quantitative comparisons. For example, as a quantitative analysis, it would be possible to do bibliometric analysis, or co-inventor analysis of patents, and examine the relationship between co-inventor data of medical doctors and engineers and other variables relevant to cooperation, such as regional data.

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[4] Michael Polanyi, Personal Knowledge: Towards a Post-Critical Philosophy, 1958. University of Chicago Press.